

What is claimed is:

1. A system for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the system comprising:  
a shape-lockable guide; and  
a plication device.

2. The system of claim 1 further comprising:  
an anchor delivery system; and  
at least one anchor.

3. The system of claim 1 further comprising a visualization element.

4. The system of claim 1, wherein the shape-lockable guide is chosen from the group consisting of shape-lockable overtubes, shape-lockable guide wires, shape-lockable inner conduits, and combinations thereof.

5. The system of claim 1, wherein the plication device comprises a tissue engaging assembly.

6. The system of claim 2, wherein the anchor delivery system is adapted to deliver a plurality of anchors without necessitating reloading.

7. The system of claim 2, wherein the anchor delivery system is adapted for reloading without completely removing the anchor delivery system from the patient.

8. The system of claim 3, wherein the visualization element is chosen from the group consisting of magnetic resonance imaging apparatus, ultrasound imaging apparatus, optical coherence tomography imaging apparatus, fluoroscopic imaging apparatus, endoscopes, colonoscopes, gastroscopes, laparoscopes, fiberscopes, videoscopes and combinations thereof.

9. The system of claim 1, wherein the medical procedure is chosen from the group consisting of diagnostic medical procedures, therapeutic medical procedures, treatment of gastroesophageal reflux disease, gastric reduction, endoscopic retrograde cholangiopancreatography, intubation of the bile duct, upper gastrointestinal endoscopy, lower gastrointestinal endoscopy, colonoscopy, flexible sigmoidoscopy, esophageal dilatation, anastomosis, liver biopsy, esophageal manometry, esophageal pH, cholecystectomy, enteroscopy, resection of lesions, resection of cancers, treatment of bleeding sites, trans-esophageal microsurgery, trans-anal microsurgery, and combinations thereof.

10. Apparatus for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the apparatus comprising:

an overtube having a flexible state that facilitates insertion of the overtube into the hollow body organ, and a rigid state wherein the overtube resists bending forces exerted on the overtube;

a mechanism selectively operable to reversibly transition the overtube between the flexible and rigid states; and

a device adapted to form tissue folds within the hollow body organ,

wherein the device may be advanced through the overtube while the overtube is disposed in the rigid state in any desired configuration within the unpredictably supported anatomy.

11. The apparatus of claim 10 further comprising a visualization element.

12. Apparatus for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the apparatus comprising:

a main body having a flexible state that facilitates insertion of the main body into the hollow body organ, and a rigid state wherein the main body resists bending forces exerted on the main body;

a mechanism selectively operable to reversibly transition the main body between the flexible and rigid states while the main body is disposed in any desired configuration; and

a device coupled to a distal region of the main body,

wherein the device is adapted to form tissue folds within the hollow body organ.

13. The apparatus of claim 12 further comprising a visualization element.

14. Apparatus for plicating tissue within a hollow body organ of tortuous or unpredictably supported anatomy, the apparatus comprising:

a guide tube;

a visualization device; and  
at least one therapeutic device,  
wherein the visualization device and the at  
least one therapeutic device are configured for passage  
through the guide tube.

15. The apparatus of claim 14, wherein the  
visualization device comprises an endoscope.

16. The apparatus of claim 14, wherein the  
guide tube is shape-lockable.

17. The apparatus of claim 14, wherein the at  
least one therapeutic device comprises a tissue engaging  
assembly.

18. The apparatus of claim 14, wherein the at  
least one therapeutic device comprises a tissue plicator.

19. The apparatus of claim 14, wherein the  
guide tube is adapted to provide the visualization device  
and the at least one therapeutic device with exposure,  
stability and flexibility.

20. The apparatus of claim 14, wherein the  
guide tube comprises first and second lumens, the  
visualization device configured for passage through the  
first lumen and the at least one therapeutic device  
configured for passage through the second lumen.

21. A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the method comprising:

advancing an overtube within the hollow body organ in a flexible state;

transitioning the overtube to a rigid state in any desired configuration;

advancing a plication device through the overtube; and

forming a tissue fold within the hollow body organ with the plication device.

22. The method of claim 21 further comprising visualizing formation of the tissue fold.

23. The method of claim 22, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube.

24. The method of claim 22, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube.

25. The method of claim 21, wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease, advancing the overtube within a hollow body organ comprises advancing the overtube through a patient's esophagus and into the patient's stomach, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the patient's gastroesophageal junction, and forming a tissue fold

comprises forming at least one tissue fold in a vicinity of the patient's gastroesophageal junction.

26. The method of claim 21, wherein the medical procedure comprises endoscopically performing gastric reduction, advancing the overtube within a hollow body organ comprises advancing an overtube through a patient's esophagus and into the patient's stomach, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a desired configuration within the patient's stomach, and forming a tissue fold comprises forming a plurality of tissue folds within the patient's stomach.

27. The method of claim 26 further comprising approximating and securing the plurality of tissue folds, thereby partitioning the patient's stomach into at least first and second chambers over at least a portion of the stomach.

28. The method of claim 26, wherein forming, approximating and securing a plurality of tissue folds further comprises:

forming, approximating and securing a first plurality of tissue folds in a first plane; and

forming, approximating and securing at least one additional plurality of tissue folds in at least one additional plane,

wherein the first plane and the at least one additional plane are substantially parallel to one another.

29. The method of claim 27, wherein partitioning the stomach into first and second chambers further comprises partitioning the stomach into a first lumen and a second chamber.

30. The method of claim 29, wherein partitioning the stomach into a first lumen and a second chamber further comprises partitioning the stomach such that the patient's gastroesophageal junction only communicates with the first lumen.

31. The method of claim 30, wherein partitioning the stomach into a first lumen comprises partitioning the stomach into a first lumen having a volume in the range of 10-50 cm<sup>3</sup>.

32. The method of claim 26, wherein forming a plurality of tissue folds further comprises forming a plurality of tissue folds inferior to the patient's gastroesophageal junction.

33. The method of claim 32, wherein forming a plurality of tissue folds further comprises forming a plurality of tissue folds having at least one tissue fold from an anterior segment of the patient's stomach and at least one tissue fold from an opposing posterior segment of the patient's stomach.

34. The method of claim 26, wherein forming a plurality of tissue folds within a patient's stomach comprises forming and securing a plurality of tissue folds disposed at substantially randomly selected locations to reduce a volume of the stomach.

35. The method of claim 26, wherein forming a plurality of tissue folds within a patient's stomach comprises forming a plurality of interconnected tissue folds around a perimeter of the patient's stomach with instruments advanced through, or coupled to, the overtube, the method further comprising approximating the plurality of interconnected tissue folds to remodel the stomach to an hourglass profile.

36. The method of claim 21, wherein the medical procedure comprises resecting a lesion or cancer within a patient's gastrointestinal tract, advancing the overtube within a hollow body organ comprises advancing the overtube through the patient's esophagus or colon, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the lesion or cancer, and forming a tissue fold comprises forming at least one tissue fold with a plication device advanced through, or coupled to, the overtube, so that the lesion or cancer is disposed on the tissue fold.

37. The method of claim 36 further comprising removing the lesion or cancer.

38. The method of claim 37, wherein removing the lesion or cancer further comprises removing the lesion or cancer with cutting apparatus.

39. The method of claim 38, wherein removing the lesion or cancer with cutting apparatus further comprises removing the lesion or cancer with a snare.



40. The method of claim 21, wherein the medical procedure comprises endoscopically treating a bleeding site within a patient's gastrointestinal tract, advancing the overtube within a hollow body organ comprises advancing the overtube through the patient's esophagus or colon, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the bleeding site, and forming a tissue fold comprises forming at least one tissue fold with a plication device advanced through, or coupled to, the overtube, so that the bleeding site is disposed on the tissue fold.

41. The method of claim 40 further comprising securing the tissue fold, thereby reducing bleeding from the bleeding site.

42. The method of claim 41, wherein securing the tissue fold further comprises securing the tissue fold with an anchor assembly.

43. A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the method comprising:

advancing a main body within the hollow body organ in a flexible state, the main body having a plication device coupled to a distal region thereof;

transitioning the main body to a rigid state in any desired configuration; and

forming a tissue fold within the hollow body organ with the plication device.

44. The method of claim 43 further comprising visualizing formation of the tissue fold.

45. The method of claim 44, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube.

46. The method of claim 44, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube.

47. The method of claim 43, wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease, advancing the main body within a hollow body organ comprises advancing the main body having a plication device coupled to a distal region thereof through a patient's esophagus and into the patient's stomach, transitioning the main body to a rigid state comprises transitioning the main body to a rigid state in a configuration that provides for engagement of tissue in a vicinity of the patient's gastroesophageal junction with the plication device, and forming a tissue fold comprises forming at least one tissue fold in the vicinity of the patient's gastroesophageal junction.

48. The method of claim 43, wherein the medical procedure comprises endoscopically performing gastric reduction, advancing the main body within a hollow body organ comprises advancing a main body having a plication device coupled to a distal region thereof through a patient's esophagus into the patient's stomach, transitioning the main body to a rigid state comprises transitioning the main body to a rigid state in a desired configuration within the patient's stomach, and forming a

tissue fold comprises forming a plurality of tissue folds within the patient's stomach.

49. The method of claim 48 further comprising approximating and securing the plurality of tissue folds, thereby partitioning the patient's stomach into at least first and second chambers over at least a portion of the stomach.